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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,123	08/28/2003	Denis Martin	PHARMA-330	5510

24995 7590 06/06/2005

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,123	MARTIN ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11-20, 21-27, and 32 drawn to a pharmaceutical composition comprising a liposome associate with at least one polypeptide comprising SEQ ID NO:2, fragments or analogs thereof, and methods of treating or preventing meningitidis and meningococcemia using said compositions, classified in class 424, subclass 249.1.

II. Claims 9 and 10, drawn to a pharmaceutical composition comprising a liposome associate with at least one polynucleotide which encodes a polypeptide having 70-100% identity to SEQ ID NO:2 and fragments and analogs thereof, classified in class 536, subclass 23.7.

III. Claim 28 and 33, drawn to a diagnostic method for detecting *N.meningitidis* comprising incubating an antibody or antibody fragment from a composition comprising a liposome associate with at least one polypeptide comprising SEQ ID NO:2, fragments or analogs thereof with a sample and detecting binding and a kit comprising said antibody, classified in class 435, subclass 7.1.

IV. Claim 30, drawn to a method for detecting *N.meningitidis* comprising incubating one or more DNA proves having a DNA encoding SEQ ID NO:2 with a biological sample and detecting binding, classified in class 435, subclass 6.

V. Claim 31, drawn to a method for detecting *N.meningitidis in vivo* comprising administering a host a labeled antibody and detecting the antibody within the host, classified in class 424, subclass 9.1.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are biologically, chemically and structurally different from one another. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide of group I. For example, the polynucleotides of Group II include variant sequences which differ by as much as 30% from the coding sequence. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. Searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the

concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polynucleotide claims include polynucleotides having 70% identity to the coding sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(b) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II together.

While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Groups II and IV are patentably distinct because the method of Group IV does not use the composition of Group II. The composition of Group II is drawn to a pharmaceutical composition comprising a liposome associate with at least one polynucleotide which encodes a polypeptide having 70-100% identity to SEQ ID NO:2 and fragments and analogs thereof, whereas the diagnostic method of Group IV does not use this pharmaceutical composition, but instead uses a DNA probe encoding SEQ ID NO:2. Additionally, the compositions of Group II could be used for methods other than diagnostic, e.g., they could be used as immunogens. The methods of Groups III and V are patentably distinct because they contain different method steps with different routes of detection. The method of Group V is an *in vivo* method requiring detection within a host. This is very different from the *in vitro* method of Group III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search required for the Groups is not coextensive, restriction for examination purposes as indicated is proper.

3. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

5/17/05